

Governor

KARYN E. POLITO Lieutenant Governor

## The Commonwealth of Massachusetts

Executive Office of Health and Human Services Department of Public Health Bureau of Health Care Safety and Quality **Medical Use of Marijuana Program** 99 Chauncy Street, 11th Floor, Boston, MA 02111

**MARYLOU SUDDERS** Secretary

MONICA BHAREL, MD, MPH Commissioner

Tel: 617-660-5370 www.mass.gov/medicalmarijuana

(Proposed - Not Final)

Title: Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-Infused Products for Massachusetts Registered Medical Marijuana Dispensaries

## Exhibit 7 (a). **Concentration Limits for Residual Solvents**

Solvent	Concentration Limit (mg/kg)
Acetic acid	5000
Acetone	5000
Acetonitrile	410
Anisole	5000
1-Butanol	5000
2-Butanol	5000
Butyl acetate	5000
Tert-Butylmethyl ether	5000
Chlorobenzene	360
Chloroform	60
Cumene	70
Cyclohexane	3880
1,2-Dichloroethene	1870
Dichloromethane	600
1,2-Dimethoxyethane	100
<i>N,N</i> -Dimethylacetamide	1090
<i>N,N</i> -Dimethylformamide	880
Dimethyl sulfoxide	5000
1,4-Dioxane	380
Ethanol	5000
2-Ethoxyethanol	160

Solvent	Concentration Limit (mg/kg)
Heptane	5000
Hexane	290
Isobutyl acetate	5000
Isopropyl acetate	5000
Methanol	3000
2-Methoxyethanol	50
Methyl acetate	5000
3-Methyl-1-butanol	5000
Methylbutylketone	50
Methylcyclohexane	1180
Methylethyl ketone	5000
Methylisobutyl ketone	5000
2-Methyl-1-propanol	5000
N-Methylpyrrolidone	530
Nitromethane	50
Pentane	5000
1-Pentanol	5000
1-Propanol	5000
2-Propanol	5000
Propyl acetate	5000
Pyridine	200

Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-Infused Products for Massachusetts Registered Medical Marijuana Dispensaries

Ethyl acetate	5000
Ethylene glycol	620
Ethyl ether	5000
Ethyl formate	5000
Formamide	220
Formic acid	5000

Sulfolane	160
Tetrahydrofuran	720
Tetralin	100
Toluene	890
1,1,2-Trichloroethylene	80
Xylene	2170

## Exhibit 7 (b). Concentration Limits for Residual Levels of Propane, n-Butane, or Iso-Butane

The Medical Use of Marijuana Program has amended the document "Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-Infused Products for Massachusetts Registered Medical Marijuana Dispensaries" to reflect the addition of the hydrocarbon gases propane, butane and iso-butane to the list of approved solvents in Exhibit 7. Analysis Requirements for Residual Solvents in Cannabis Oil.

Solvent*	Upper Limit (mg/kg)
Propane (CAS 74-98-6)	1
n-Butane (CAS 106-97-8)	1
Iso-Butane (CAS 75-28-5)	1

<sup>\*</sup>The ingredients must be of purity suitable for use in food intended for human consumption. At a minimum, the solvent (gas) must be high-purity (>99%) of propane, n-butane, or isobutane, or a blend these three hydrocarbon gases.

The upper limits are based on residual solvent recommendation by the Commission of the European Communities, Scientific Committee on Food (SCF, 1999). SCF has evaluated propane, n-butane and iso-butane as extraction solvents and determined that a residue level of 1mg of residual hydrocarbon per kg of food consumed is safe. The SCF evaluation suggests that these hydrocarbons are typically present in prepared foods in amounts less than 0.1 mg/kg. After careful review of the SCF assessment, MDPH has adopted a level of 1 mg/kg (or 10 times the background level of 0.1 mg/kg) as a health-protective residual solvent limit for cannabis oil.

Source: MDPH August 17, 2015 Circular Letter: DHCQ 15-08-638 http://www.mass.gov/eohhs/docs/dph/quality/medical-marijuana/dph-hydrocarbons.pdf